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VOGEL, N EXAMINER

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-37 are pending in the application.
   Of the above, claims 19, 20, 36 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-18, 21-35 and 37 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-18, 21-35 and 37, drawn to methods of immunization, classified, for example, in Class 424, subclass 88.

II. Claims 19-20, drawn to a kit and an immunogenic agent, classified, for example, in Class 424, subclass 88.

III. Claim 36, drawn to a method of screening at least one potentially pharmaceutically acceptable dose for the ability to modulate the development of at least one chronic immune mediated disorder, classified, for example in Class 424, subclass 88.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process, such as in a process of identifying levels of circulating antibodies in a patient. Inventions of Groups I and III are distinct methods, having no features in common.

Because these inventions are distinct for the reasons given

above and the Groups have acquired a separate status in the art as shown by their divergent subject matter and because separate searches of the non-classified literature would be required, restriction for examination purposes as indicated is proper.

During a telephone conversation between Examiner Nancy T. Vogel and Attorney Iver Cooper on 1/26/94 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-18, 21-35, and 37. Affirmation of this election must be made by applicant in responding to this Office action. Claims 19, 20, and 36 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification fails to teach a method of pediatric immunization against a chronic immune mediated disorder.

Although the specification provides guidance for the immunization of mice which apparently results in a decreased incidence of diabetes, it fails to teach a method of immunization of humans which result in the claimed effect of reduction of incidence, frequency, prevalence or severity of any chronic immune mediated disorder.

Claims 17, and 21-35 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-16, 18 and 37 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with the specification, which discloses a method of immunizing NOD mice which decreases the incidence of diabetes mellitus. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The claims are broadly drawn to a method of immunizing any mammal against any infectious disease and any chronic immune-mediated disorder, comprising administering any immunogens other than BCG, wherein the first dose is before 42 days after birth, and wherein the immunogens act to substantially reduce the chronic immune-mediated disorder. The specification only provides guidance for a method of immunizing mice with anthrax or plague vaccine at days 8, 15, and 29 of life (page 78 of the specification); or a method of immunizing mice with anthrax,

combined with diphtheria tetanus, or with the combined whole cell pertussis diphtheria tetanus vaccine as disclosed in Examples 2 and 3 (pages 79-82); wherein a reduction of the incidence or severity of at least one chronic immune-mediated disorder results. It cannot be predicted that other mammals would respond similarly to the mice used in the disclosed experiments. It cannot be predicted that other immunogens would yield similar results. It cannot be predicted that other schedules of immunization would yield similar results. It cannot be predicted what amounts of immunogens would yield similar results. Applicants have claimed methods of immunization comprising a large number of permutations of vaccination schedules and immunogens, which have the effect of reducing the incidence, prevalence, frequency or severity of any chronic immune mediated disorder. It is noted that the term "chronic immune mediated disorder" comprises perhaps hundreds or thousands of diseases ranging from hay fever to cancer. It is maintained that it would require undue experimentation to determine vaccination schedules, and types and amounts of immunogens, which would have the claimed effect on any particular mammal, due to the lack of guidance in the specification and the very large numbers of possible variations embodied by the claims. Therefore, the claims should be limited to the particular methods exemplified in the specification.

Claims 9 and 21-35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is vague and indefinite in its recitation of "the method of claim wherein said..." In order to expedite prosecution, the claim has been examined as if it were dependent on claim 1.

Claims 21-35 are vague and indefinite in their recitation of "In a method for pediatric immunization" and "comprising administering...to a mammal". Pediatric immunization clearly is limited to the immunization of humans, not any mammal. It is noted that the claims have been examined as a method of pediatric immunization.

Claims 21-35 are indefinite, since it cannot be determined what applicants intend to claim. It is not clear how many doses of the recited vaccine are intended, and when they are intended to be administered. It is not clear how one dose can be comprised of more than one doses, as is recited in the claims. The claims should be amended to clarify the intended subject matter.

Claim 22 lacks antecedent basis in claim 21 for the term "said mammal of at least 28 days of age but less than 175 days of age". The claim is unclear in its recitation of "said at least

one dose comprises a total of at least 4 separate...doses". It is not clear how one dose can be comprised of 4 doses.

Claim 31 is vague and indefinite in the recitation of "at least one pharmaceutically acceptable immunogen at least 11 days, but less than 26 days, after the last dose of said immunogen proceeding 26 days of age of said mammal". It is not known what is intended by this phrase.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-16, 18, are rejected under 35 U.S.C. § 102(b) as being anticipated by Lee (U.S. Pat. No. 4,857,318) (A).

Lee discloses a method of immunizing a mammal less than 96 months of age against at least one infectious disease comprising administering to said mammal a vaccine against Bordatella pertussis at 7 and 21 days of age (see column 8, lines 12-13), or at 6 and 12 days of age (column 10, lines 8-15). Although not tested in the references, it is considered that the methods disclosed in the reference would inherently produce the claimed effect of reduction of incidence or severity of at least one

chronic immune-mediated disorder, since the immunogen is administered prior to 42 days of age.

Claims 1, 2, 4, 6, 7, 9-16, and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Green et al (U.S. Pat. No. 4,625,015) (B).

Green et al disclose a method of immunizing a mammal less than 96 months of age against at least one infectious disease comprising administering to said mammal an influenza immunogen at 28, 42 and 56 days of age (see column 11, lines 55-59). Although not tested in the references, it is considered that the methods disclosed in the reference would inherently produce the claimed effect of reduction of incidence or severity of at least one chronic immune-mediated disorder, since the immunogen is administered prior to 42 days of age.

Claims 1, 2, 4-7, and 9-16, are rejected under 35 U.S.C. § 102(a) as being anticipated by Kuzuhara et al (U.S. Pat. No. 5,151,023) (C).

Kuzuhara et al disclose a method of immunizing a mammal less than 96 months of age against at least one infectious disease comprising administering to said mammal a hepatitis A and hepatitis B immunogen at 28 days of age (see column 7, 28-35). Although not tested in the reference, it is considered that the methods disclosed in the reference would inherently produce the

claimed effect of reduction of incidence or severity of at least one chronic immune-mediated disorder, since the immunogen is administered prior to 42 days of age.

Claims 1, 2, and 7-17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Dengrove et al (cited by applicants).

Dengrove et al disclose a method of pediatric immunization against three infectious diseases, wherein one dose of DTP vaccine is administered at less than 42 days of age. Although not disclosed in the reference, it is considered that the methods disclosed in the reference would inherently produce the claimed effect of reduction of incidence or severity of at least one chronic immune-mediated disorder, since the immunogen is administered prior to 42 days of age.

Claims 1, 2, and 7-17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Baraff et al (cited by applicants).

Baraff et al disclose a method of pediatric immunization against three infectious diseases, wherein one dose of DTP vaccine is administered at less than 42 days of age. Although not disclosed in the reference, it is considered that the methods disclosed in the reference would inherently produce the claimed effect of reduction of incidence or severity of at least one chronic immune-mediated disorder, since the immunogen is administered prior to 42 days of age.

Claims 1, 2, 7, 8, 11-17 are rejected under 35 U.S.C. § 102(b) as being anticipated by John et al (cited by applicants).

John et al disclose a method of pediatric immunization against at least one infectious disease, wherein two doses of poliomyelitis vaccine is administered at less than 42 days of age. Although not disclosed in the reference, it is considered that the methods disclosed in the reference would inherently produce the claimed effect of reduction of incidence or severity of at least one chronic immune-mediated disorder, since the immunogen is administered prior to 42 days of age.

Claims 1, 2, 7, 9-17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Madore et al (cited by applicants).

Madore et al disclose a method of pediatric immunization against at least one infectious disease, wherein a dose of hemophilus influenza vaccine is administered at less than 42 days of age. Although not disclosed in the reference, it is considered that the methods disclosed in the reference would inherently produce the claimed effect of reduction of incidence or severity of at least one chronic immune-mediated disorder, since the immunogen is administered prior to 42 days of age.

Claims 1, 2, 4, 5, 7, 8, and 10-16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Oldstone et al (Science) (cited by applicants).

Oldstone et al disclose a method of pediatric immunization against an infectious disease, wherein a dose of LCMV vaccine is administered at less than 42 days of age. The reference discloses that Type I diabetes is prevented.

Any inquiry concerning this communication should be directed to Nancy Vogel, Ph.D. at telephone number (703) 308-0278.

Nancy Vogel
Patent Examiner